Certificate No: **GMP 269/4**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with the requirements of Good Manufacturing Practice, of the Israeli laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products] 2008)

and

Issued under the provisions of the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel

The competent authority of Israel confirms the following:

The manufacturer **Milouda Laboratories Limited Partnership**
M.P. Ashrat, 1032900, Israel

Site address **1 HaBrosh St,. Bar Lev Ind. Park, M.P. Misgav, 2015600, Israel**

Has been inspected under the Israeli inspection programme, in accordance with the above mentioned laws and regulations

and

Is a contract laboratory which is authorized to perform microbiological QC testing of pharmaceuticals

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **12, 13 May 2025,** it is considered that it complies with the Good Manufacturing Practice requirements referred to in the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel and the above mentioned Israeli laws and regulations (*).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than **three years** have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP.
If it does not appear, please contact the issuing authority.

(*) these requirements fulfill the GMP recommendations of WHO

MINISTRY OF HEALTH JERUSALEM
GOV. INSTITUTE FOR CONTROL AND STANDARD OF PHARMACEUTICALS
משרד הבריאות

16.7.25

מיכאל כרמי
ע. מפקח ארצי
תואר יצור נאותים

Ministry Of Health, MTIR Directorate
The Institute for Standardization and Control of Pharmaceuticals
9 Ya'akov Eli'av St., Jerusalem, 9546208, Israel
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רח' יעקב אליאב 9, ירושלים 9546208
טל: 02-6551717, פקס: 02-6551777

Part 2

1.	**MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS**
	1.6 Quality control testing
	1.6.2 Microbiology: non-sterility *(microbiological examination of non- sterile products)*

Any restrictions or clarifying remarks related to the scope of this certificate

The lacoratory is authorized to perform microbiological QC testing (microbiological examination of non- sterile products) of pharmaceuticals for other parties

Name and signature of the authorized person of the Competent Authority of Israel

Michael Carmi, Pharmacist, GMP inspector

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